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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,451	02/28/2002	Chaitan Khosla	286002021121	1435

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EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 01/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/087,451

Applicant(s)

KHOSLA ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Application Status

1. Claims 1-25 are pending in the instant application.

Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
 - I. Claim 1, drawn to modified microbial host cells that produce polyketides modified by the inclusion of an expression system for a starter/extender unit, etc., classified in class 435, subclass 252.3.
 - II. Claims 2-3, drawn to methods of making polyketides using cells with expression systems for starter units, etc., classified in class 435, subclass 76.
 - III. Claim 4, drawn to methods of determining a substituted benzoate's ability to prime an A-T didomain of rifamycin synthetase, classified in class 435, subclass 183.
 - IV. Claims 5-7 and 12-18, drawn to prokaryotic host cells modified to express an A-T didomain, classified in class 435, subclass 252.3.
 - V. Claims 8-10, drawn to hybrid polyketides, classified in class 568, subclass 382.
 - VI. Claims 11 and 19, drawn to methods of making polyketides with an A-T didomain, classified in class 435, subclass 76.
 - VII. Claims 20-22, drawn to methods to enhance production of secondary metabolites using timely induction procedures, classified in class 435, subclass 41.
 - VIII. Claims 23-24, drawn to methods to enhance production of secondary metabolites using constant nutrient levels, classified in class 435, subclass 41.
 - IX. Claim 25, drawn to methods to enhance polyketide production using a TEII expression system, classified in class 435, subclass 76.

3. The inventions are distinct, each from the other because of the following reasons:

Groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the products can be used for a materially different process of

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using that product, such as recombinantly producing proteins for purification, wherein said proteins produce starter and/or extender units such as the recombinant production of propionyl-CoA synthetase. Thus, Groups I and II are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups I and II are related to Groups III-VI by virtue of their relation to the production of polyketides. However, Groups I-II are specific to host cells with expression systems for proteins that produce starter and/or extender units while Groups III-VI are specific to host cells with expression systems for proteins that can utilize a substituted benzoate to prime an A-T didomain. Thus, these products and related methods are wholly distinct based on their distinct structures and functions and/or their distinct method steps, particular using distinct reagents. Therefore, Groups I-II are patentably distinct from Groups III-VI, each from the other. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Wherein the classifications are the same, the same search is not required due to the distinct subject matter requiring a separate keyword search, thus, restriction for examination purposes as indicated is proper.

Groups I-II are related to Groups VII-IX by virtue of their relation to the production of polyketides. However, Groups I-II are specific to host cells with expression systems for proteins that produce starter and/or extender units while Groups VII-IX are specific to methods using particular culture conditions and/or a TEII expression system. Therefore, Groups I-II are patentably distinct from Groups VII-IX, each from the other. Because these inventions are

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distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Wherein the classifications are the same, the same search is not required due to the distinct subject matter requiring a separate keyword search, thus, restriction for examination purposes as indicated is proper.

Group III is related to Group IV by virtue of their relation to A-T didomains. However, Group III does not require host cells or expression, which would relate specifically to the products of Group IV. Thus, Groups III and IV are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Group III is related to Group V by virtue of their relation to A-T didomains, which are useful in production of the polyketides of Group I. However, Group III does not make or use the polyketides of Group V. Thus, Groups III and V are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups III and VI are related as methods using A-T didomains. However, the methods are distinct because they contain distinct methods steps using distinct reagents to produce distinct products. Specifically, Group III does not require expression systems. Thus, Groups III and VI are patentably distinct. . Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups IV and V are related because the host cells of Group IV produce polyketides as claimed in Group V. Although the host cells can be used to produce the polyketides, the host cells themselves and polyketides are wholly distinct products with distinct structures and functions. Thus, Groups IV and V are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the host cells can be used for a materially distinct process of using the product, such as in recombinant production of an A-T didomain protein for purification. Thus, Groups IV and VI are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups V and VI are related because Group VI produced polyketides and Group V are polyketides. However, the polyketides of Group V need not be produced by the methods of Group VI. Thus, Groups V and VI are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups III-VI are related to Groups VII-IX by virtue of their relation to the production of polyketides. However, Groups III-VI are specific to host cells with expression systems for

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proteins that can utilize a substituted benzoate to prime an A-T didomain while Groups VII-IX are specific to methods using particular culture conditions and/or a TEII expression system.

Therefore, Groups III-VI are patentably distinct from Groups VII-IX, each from the other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Wherein the classifications are the same, the same search is not required due to the distinct subject matter requiring a separate keyword search, thus, restriction for examination purposes as indicated is proper.

Groups VII and VIII are related as methods of producing secondary metabolites using specific culturing conditions. However, the specific conditions are distinct for Groups VII and VIII, thus, rendering distinct methods. Therefore, Groups VII and VIII are patentably distinct. Because these inventions are distinct for the reasons given above and the search required for Group VII is not required for Group VIII, restriction for examination purposes as indicated is proper.

Groups VII and VIII are related to Group IX because all the methods produce polyketides. However, they are distinct because Groups VII and VIII use specific culture conditions while Group IX using a specific expression system in the culture. Therefore Groups VII and VIII are patentably distinct from Group IX. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Election of Species

4. This application contains claims directed to the following patentably distinct species of the claimed invention: in Claims 8-10 (Group V), polyketides having particular starter units as defined in Claim 9. These species are distinct because of their distinct structures.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 8 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

Notice of Possible Rejoinder

5. The Examiner notes that if product claims in Groups I or IV are found directed to an allowable product, then process claims in Groups II or VI, respectively, which are directed to processes of using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, would now be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. § 821.04, *In re* Ochiai, and *In re* Brouwer). Since process claims would be rejoined and fully examined for patentability under 37 C.F.R. § 1.104, Applicants are instructed to amend said claims as deemed necessary according to rejections made against the elected claims.

Election

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143). If Group V is elected, an election of species is also required.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

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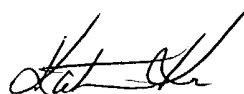
Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229.

The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Kathleen M Kerr
Examiner
Art Unit 1652

January 15, 2004